

Serial No.: 08/469,492  
Examiner: B. Prickril

**IN THE CLAIMS:**

(All claims are reproduced below for the Examiner's convenience. Claims that have not been amended are indicated as "Unchanged". Claims that have been cancelled herein are indicated as "Cancelled".)

C1  
37. (Amended) A method for treating an autoimmune disease in a human, the method comprising administering by nose or mouth to said human an effective amount for treating said disease of a composition comprising a bystander antigen, [said antigen eliciting suppressor T-cells which cause the release of transforming growth factor beta (TGF- $\beta$ ) at a locus within the body of said human, wherein T cells contributing to autoimmune response are located, and thereby suppress the T-cells contributing to said response,] wherein said bystander antigen is not an autoantigen in said human and wherein said bystander antigen is not an insulin antigen [said administration is not effective to treat said disease non-immunologically].

38. (Unchanged) The method of claim 37 wherein said bystander antigen is specific to an organ or tissue afflicted by immune attack during said disease.

C2  
39. (Amended) [The method of claim 38] A method for treating an autoimmune disease in a human, the method comprising administering by nose or mouth to said human an effective amount for treating said disease of a composition comprising a

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*C2*  
*concl* bystander antigen, wherein said bystander antigen is not an autoantigen, and wherein said  
bystander antigen is not an insulin antigen.

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Cancel claims 40-41.

40. (Cancelled) The method of claim 38 wherein said bystander antigen is an autoantigen.

41. (Cancelled) The method of claim 38 wherein said bystander antigen comprises a portion of an autoantigen but excludes at least one epitope of said autoantigen that is recognized by immune system cells contributing to said disease.

42. (Unchanged) The method of claim 37 wherein said bystander is administered to said human in aerosol form.

43. (Unchanged) The method of claim 37 wherein said bystander antigen is administered in a dry powder form.

44. (Unchanged) The method of claim 37 wherein said bystander antigen is administered as a saline solution.

45. (Amended) The method of claim 38 wherein said administration is effective to treat said disease without causing an accompanying [substantial] decrease in the blood sugar level of said human.

46. (Amended) The method of claim 38 wherein said disease is [selected from the group consisting of] Type I diabetes [and animal models therefor] and said bystander antigen is glucagon.

C3  
47. (Amended) [The method of claim 38 wherein said disease is selected from the group consisting of] A method for treating type I diabetes in a human, the method comprising administering by inhalation to said human an effective amount for treating said Type I diabetes [and animal models therefor and said bystander antigen is] of [gamma amino] glutamic acid decarboxylase.

48. (Amended) A pharmaceutical [inhalation] dosage form for nasal or mouth administration and for treating an autoimmune disease in a human, the form consisting essentially of:

an effective amount for treating said disease of a bystander antigen,  
[said antigen upon administration eliciting suppressor T-cells that cause the release of transforming growth factor beta (TGF- $\beta$ ) at a locus within the body of said human wherein T

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cells contributing to autoimmune response are found to suppress the T-cells contributing to said response]; and

a pharmaceutically acceptable carrier or diluent[,];

*C3*  
*cancel* wherein said [dosage form is not effective to treat said autoimmune disease non-immunologically] bystander antigen is not an autoantigen in said human.

49. (Amended) The pharmaceutical [inhalable] dosage form for nasal or mouth administration of claim 48 wherein said bystander antigen is specific to an organ or tissue afflicted by immune attack during said disease.

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Cancel claims 50 and ~~51.~~

50. (Cancelled) The inhalable dosage form of claim 49 wherein said bystander antigen is not an autoantigen.

51. (Cancelled) The inhalable dosage form of claim 49 wherein said bystander antigen is an autoantigen.

52. (Amended) The pharmaceutical [inhalable] dosage form for nasal or mouth administration of claim 49 wherein said dosage form is an aerosol form.

53. (Amended) The pharmaceutical [inhalable] dosage form for nasal or mouth administration of claim 49 wherein said dosage form is a saline solution.

54. (Amended) The pharmaceutical [inhalable] dosage form for nasal or mouth administration of claim 49 wherein said dosage form is a dry powder.

55. (Amended) The pharmaceutical [inhalable] dosage form for nasal or mouth administration of claim 49 wherein said dosage form is effective to treat said autoimmune disease without causing a [substantially] lowering of the blood sugar level of said human.

56. (Amended) The pharmaceutical [inhalable] dosage form for nasal or mouth administration of claim 48 wherein said disease is selected from the group consisting of Type I diabetes and animal models therefor and said bystander antigen is glucagon.

57. (Amended) [The inhalable dosage form of claim 48 wherein said disease is selected from the group consisting of] A pharmaceutical dosage form for nasal or

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Sub E2  
cont

cancel  
mouth administration for treating Type I diabetes in a human [and animal models therefor and said bystander antigen is] comprising an effective amount for treating said type I diabetes of [gamma amino] glutamic acid decarboxylase and a pharmaceutically acceptable carrier or diluent.

Cancel claim 58.

58. (Cancelled) The inhalable dosage form of claim 49 wherein said bystander antigen comprises a portion of an autoantigen comprising an immunosuppressive epitope but excludes at least one epitope of said autoantigen that is recognized by immune system cells contributing to said disease.

Kindly add the following claims:

--59. The method of claim 37 wherein said bystander antigen is purified.

CS  
--60. The method of claim 37 wherein said bystander antigen is substantially pure.

--61. The method of claim 37 wherein said composition is substantially free of autoantigens.

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--62. The pharmaceutical dosage form of claim 48 wherein said bystander antigen is purified.

--63. The pharmaceutical dosage form of claim 48 wherein said bystander antigen is substantially pure.

--64. The pharmaceutical dosage form of claim 48 wherein said composition is substantially free of autoantigens.

--65. A method for treating an autoimmune disease in a human, the method comprising administering by nose or mouth to said human an effective amount for treating said disease of a composition comprising a bystander antigen, wherein said bystander antigen is not an antigen to which T-cells which mediate the disease are sensitized, and wherein said bystander antigen is not an insulin antigen.

#### REMARKS

Reconsideration of this application is respectfully requested.